## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 9, 2017

## FibroGen, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-36740 (Commission File Number) 77-0357827 (IRS Employer Identification No.)

FibroGen, Inc. 409 Illinois Street

A09 Ininois Street San Francisco, CA 94158 (Address of principal executive offices, including zip code)

(415) 978-1200

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

#### Item 2.02 Results of Operations and Financial Condition.

On May 9, 2017, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended March 31, 2017. A copy of such press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in Exhibit 99.1 shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by FibroGen, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description   |
|-------------|---|
| 99.1        | Press Release titled "FibroGen Reports First Quarter 2017 Financial Results," dated May 9, 2017 |

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

FIBROGEN, INC.

Dated: May 9, 2017

By: /s/ Pat Cotroneo

Pat Cotroneo Vice President, Finance and Chief Financial Officer

#### INDEX TO EXHIBITS

| Exhibit No. | Description   |
|-------------|---|
| 99.1        | Press Release titled "FibroGen Reports First Quarter 2017 Financial Results," dated May 9, 2017 |

#### FIBROGEN REPORTS FIRST QUARTER 2017 FINANCIAL RESULTS -Conference Call and Webcast to be Held Today at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time-

SAN FRANCISCO, May 9, 2017 -- FibroGen, Inc. (NASDAQ: FGEN), a science-based biopharmaceutical company, today reported financial results for the first quarter of 2017 and provided an update on the company's recent developments.

"This is an exciting time for FibroGen, as we prepare for an eventful second half of the year across our pipeline. In the third quarter of 2017, we anticipate reporting topline Phase 2 clinical trial results for pamrevlumab in idiopathic pulmonary fibrosis patients, and we are preparing to complete submission of the roxadustat China NDA for the treatment of anemia in non-dialysis and dialysis CKD patients," said Thomas B. Neff, FibroGen's Chief Executive Officer. "We are gratified by the support we received from new and current investors in our recent equity offering, which raised \$115.1 million in net proceeds. This financing will support our plans to increase the number of studies and accelerate development in other anemia categories in China, including for roxadustat in anemias in certain oncology settings."

#### RECENT DEVELOPMENTS AND HIGHLIGHTS

#### U.S. Roxadustat for Anemia in Chronic Kidney Disease (CKD)

- The independent data safety monitoring board (DSMB) recommended in April that all trials continue with no modifications to current protocols.
- On track to submit the NDA for roxadustat in the U.S. in 2018.

#### U.S. Roxadustat for Anemia in Myelodysplastic Syndromes (MDS)

- Received approval from FDA to conduct Phase 3 study for the treatment of anemia in MDS.
- This study is planned to start in the third quarter of 2017.

#### China Roxadustat Anemia in CKD: Dialysis and Non-Dialysis

- Positive Phase 3 results from two pivotal trials in China were announced on January 30, 2017.
- On target for NDA submission in China in the third quarter of 2017.

#### China Roxadustat for Myelodysplastic Syndromes (MDS)

- Received approval from the CFDA to undertake a Phase 2/3 study for the treatment of anemia in MDS.
- We plan to start this study in the fourth quarter of 2017.

#### Pamrevlumab in Idiopathic Pulmonary Fibrosis (IPF)

• On track to report topline Phase 2 study results from a double-blind, placebo-controlled study, and a double-blind, active-controlled sub-study for the treatment of IPF in the third quarter of 2017.

#### Pamrevlumab in Pancreatic Cancer

- Positive findings from an ongoing open-label, randomized Phase 1/2 study in locally advanced pancreatic cancer were presented at the 2017 Gastrointestinal Cancers Symposium in January.
- Positive results from a prior Phase 1/2 trial were published online in January 2017 in the Journal of Cancer Clinical Trials.

#### **Corporate and Financial Highlights**

- Net loss per basic and diluted share for the quarter ended March 31, 2017 was \$0.52, as compared to \$0.45 a year ago.
- At March 31, 2017, FibroGen had \$314.2 million of cash, restricted time deposits, cash equivalents, investments, and receivables.
- In addition, we completed an equity financing on April 11, 2017 that generated \$115.1 million in net proceeds.

#### **Conference Call Details**

FibroGen will host a conference call and webcast today, May 9, 2017, at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time), to discuss financial results and provide a business update. Interested parties may access a live audio webcast of the conference call via the investor section of the FibroGen website, www.fibrogen.com. To access the conference call by telephone, please dial 1 (888) 771-4371 (U.S. and Canada) or 1 (847) 585-4405 (international), reference the FibroGen First Quarter 2017 conference call, and use the confirmation number 44595888. It is recommended that listeners register 15 minutes before the scheduled start time to ensure a timely connection. A replay of the webcast will be available shortly after the call for a period of two weeks. To access the replay, please dial (888) 843-7419 (domestic) or (630) 652-3042 (international), and use the confirmation number 4459 5888#.

#### **About Roxadustat**

Roxadustat (FG-4592) is a first-in-class, orally administered small molecule currently in global Phase 3 clinical development as a potential therapy for anemia associated with chronic kidney disease (CKD). Roxadustat is a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) that promotes erythropoiesis through increasing endogenous erythropoietin, improving iron regulation, and reducing hepcidin. Administration of roxadustat has been shown to induce coordinated erythropoiesis – increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range in multiple subpopulations of CKD patients – including in the presence of inflammation and without a need for supplemental intravenous iron.

Roxadustat is currently advancing through Phase 3 clinical trials worldwide, supported by extensive Phase 2 clinical data demonstrating correction and maintenance of hemoglobin levels in multiple subpopulations of CKD anemia patients. To date, roxadustat has been evaluated in Phase 1 and Phase 2 studies involving more than 1,400 subjects. Globally, a total of 17 studies are currently underway involving a total of more than 11,000 patients. Of these, 15 are Phase 3 pivotal studies comprising 10,400 patients, and are currently being conducted to support independent regulatory approvals of roxadustat in both non-dialysis and dialysis CKD patients in the U.S., Europe, Japan, and China. Later this year, roxadustat will also enter a Phase 3 clinical trial in the U.S., and a Phase 2/3 trial in China, for the treatment of anemia in patients with myelodysplastic syndromes (MDS). For information about roxadustat studies currently recruiting patients, please visit <u>www.clinicaltrials.gov</u>.

#### **About Pamrevlumab**

Pamrevlumab (FG-3019) is an investigational therapeutic antibody developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF), a common factor in chronic fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. FibroGen is currently conducting clinical studies of pamrevlumab in idiopathic pulmonary fibrosis, pancreatic cancer, and Duchenne muscular dystrophy (DMD). In desmoplastic or fibrotic cancers, such as pancreatic cancer, CTGF in the extensive fibrous stroma associated with the tumor promotes abnormal proliferation of stromal cells and tumor cells. Studies in a transgenic mouse model of pancreatic cancer indicate that treatment with pamrevlumab in combination with chemotherapy may enhance the efficacy of chemotherapy and improve survival. For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

#### About FibroGen, Inc.

FibroGen, Inc., headquartered in San Francisco with subsidiary offices in Beijing and Shanghai, PRC, is a leading science-based biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in fibrosis and hypoxia-inducible factor (HIF) biology and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat, the company's most advanced product candidate, is an oral small molecule inhibitor of HIF prolyl hydroxylase activity in Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD) and is entering Phase 3 development for anemia in lower risk myelodysplastic syndromes (MDS). Pamrevlumab, a fully-human monoclonal antibody that inhibits the activity of connective tissue growth factor (CTGF), is in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), pancreatic cancer, and Duchenne muscular dystrophy (DMD). FibroGen is also developing a biosynthetic cornea in China. For more information, please visit www.fibrogen.com

#### **Forward-Looking Statements**

This release contains forward-looking statements regarding our strategy, future plans and prospects, including statements regarding the development of the Company's product candidates, roxadustat and pamrevlumab, the potential safety and efficacy profile of our product candidates, the timelines for reporting of our clinical data reporting, potential milestones, and regulatory submissions, our clinical plans and our financial projections. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. Our actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of our various non-clinical and clinical programs, including enrollment of our Phase 3 trials and other clinical trials, and our collaboration partners' clinical trials for roxadustat in anemia associated with CKD, the continued progress of our plans and programs in China, clinical development of and regulatory filing outcomes for anemia associated with myelodysplastic syndrome, the enrollment and results from ongoing clinical trials for pamrevlumab in IPF, and pancreatic cancer, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement in this press rele

#### **Condensed Consolidated Balance Sheets**

(In thousands)

| (In thousands)  | March 31, 2017 |         | December 31, 2016 |         |
|---|----------------|---------|-------------------|---------|
|   | (Unaudited)    |         | (1)               |         |
| Assets  | ( )            | ,       |                   | (-)     |
| Current assets:   |                |         |                   |         |
| Cash and cash equivalents   | \$             | 170,598 | \$                | 173,782 |
| Short-term investments  |                | 72,824  |                   | 79,397  |
| Accounts receivable   |                | 7,248   |                   | 10,448  |
| Prepaid expenses and other current assets                             |                | 5,911   |                   | 2,889   |
| Total current assets  |                | 256,581 |                   | 266,516 |
| Restricted time deposits  |                | 6,217   |                   | 6,217   |
| Long-term investments   |                | 53,155  |                   | 71,010  |
| Property and equipment, net   |                | 122,818 |                   | 123,657 |
| Other assets  |                | 2,985   |                   | 2,152   |
| Total assets  | \$             | 441,756 | \$                | 469,552 |
| Liabilities, stockholders' equity and non-controlling interests       |                |         |                   |         |
| Current liabilities:  |                |         |                   |         |
| Accounts payable  | \$             | 2,950   | \$                | 6,223   |
| Accrued liabilities   |                | 49,179  |                   | 50,914  |
| Deferred revenue  |                | 7,984   |                   | 7,988   |
| Total current liabilities   |                | 60,113  |                   | 65,125  |
| Long-term portion of lease financing obligations                      |                | 97,536  |                   | 97,352  |
| Product development obligations                                       |                | 15,152  |                   | 14,854  |
| Deferred rent   |                | 4,075   |                   | 4,212   |
| Deferred revenue, net of current                                      |                | 108,068 |                   | 106,709 |
| Other long-term liabilities   |                | 5,840   |                   | 6,191   |
| Total liabilities   |                | 290,784 |                   | 294,443 |
| Total stockholders' equity  |                | 131,701 |                   | 155,838 |
| Non-controlling interests   |                | 19,271  |                   | 19,271  |
| Total equity  |                | 150,972 |                   | 175,109 |
| Total liabilities, stockholders' equity and non-controlling interests | \$             | 441,756 | \$                | 469,552 |

(1) The condensed consolidated balance sheet amounts at December 31, 2016 are derived from audited financial statements.

# **Condensed Consolidated Statements of Operations** (In thousands, except per share data)

|   | Three Months Ended March 31, |          |        |          |  |
|---|------------------------------|----------|--------|----------|--|
|   |                              | 2017     |        | 2016     |  |
|   |                              | (Unaud   | dited) |          |  |
| Revenue:  |                              |          |        |          |  |
| License and milestone revenue   | \$                           | 19,581   | \$     | 19,738   |  |
| Collaboration services and other revenue  |                              | 7,310    |        | 8,544    |  |
| Total revenue   |                              | 26,891   |        | 28,282   |  |
| Operating expenses:   |                              |          |        |          |  |
| Research and development  |                              | 46,732   |        | 43,650   |  |
| General and administrative  |                              | 11,530   |        | 11,417   |  |
| Total operating expenses  |                              | 58,262   |        | 55,067   |  |
| Loss from operations  |                              | (31,371) |        | (26,785) |  |
| Interest and other, net:  |                              |          |        |          |  |
| Interest expense  |                              | (2,375)  |        | (2,777)  |  |
| Interest income and other, net  |                              | 645      |        | 1,416    |  |
| Total interest and other, net   |                              | (1,730)  |        | (1,361)  |  |
| Loss before income taxes  |                              | (33,101) |        | (28,146) |  |
| Provision for (benefit from) income taxes   |                              | 60       |        | (305)    |  |
| Net loss  | \$                           | (33,161) | \$     | (27,841) |  |
| Net loss per share - basic and diluted  | \$                           | (0.52)   | \$     | (0.45)   |  |
| Weighted average number of common shares used to calculate net loss per share - basic and diluted |                              | 64,037   |        | 62,184   |  |
|   |                              |          |        |          |  |

Contact

FibroGen, Inc. Karen L. Bergman VP, Investor Relations and Corporate Communications +1 (415) 978-1433 kbergman@fibrogen.com (415) 978-1433